NeuralGlider®

Neural Implant Inserter

Operator's Manual

ACTUATED MEDICAL®

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- Disregarding the cautions and instructions presented in this manual constitutes abnormal use and can result in injury.
- For use with the NeuralGider Inserter Model 101.

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Keep this manual in a safe location for future reference.

NeuralGlider®

Operator Assistance Information

If you have questions regarding the use of NeuralGlider, please contact:

Customer Service Department at Actuated Medical, Inc.
310 Rolling Ridge Drive, Bellefonte, PA 16823
Phone +1 (814) 355-0003 ext. 117 / Fax +1 (814) 355-1532

Monday through Friday
8:00 am - 5:00 pm U.S.A. Eastern Standard Time

Training Materials

Training materials are accessible on our website at ***NeuralGlider.com***.

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Figures & Tables

1.0 Intended Use

1.1) **Indications for Use**
The NeuralGlider Inserter is a device for assisting qualified personnel in performing insertions of neural implants for the study of neural function in animal models.

1.2) **Contraindications**
Do NOT use the NeuralGlider Inserter Model 101 if:

- You are performing neural implant insertions on a human.
- You are not qualified to perform neural implant procedures in animal models.
- The animal is showing signs of illness or injury.
- The site you desire to insert the neural implant contains abnormalities.

2.0 Cautions

⚠	Attention, read instructions before use. Disregarding the cautions and instructions presented in this manual constitutes ABNORMAL USE.
⚠	Do not use the NeuralGlider Inserter on humans.
⚠	Modification of this equipment is not permitted.
	Do **NOT** operate in the presence of flammable anesthetics. (Flammable anesthetics are gases or vapors, including, but not limited to, fluroxene, ethyl chloride, ethyl ether and ethylene, which may form flammable or explosive mixtures with air, oxygen or reducing gases such as nitrous oxide.)

Due to the diverse landscape of neural implants, Actuated Medical, Inc. cannot gaurantee improved insertion for all implant types. Use of the NeuralGlider Inserter is at the Operator's Discretion, and Actuated Medical, Inc. is not responsible for any damage to implants.

3.0 Operator Profile

The NeuralGlider Inserter is intended for use by Laboratory Technicians, Laboratory Supervisors and Managers, and Research Scientists. Read the Operator's Manual for training.

For more information, contact Actuated Medical's Customer Service Department at **814-355-0003 ext. 117** or visit the website **NeuralGlider.com**.

4.0 Device Description

The NeuralGlider Inserter is a device for assisting qualified personnel in performing insertions of neural implants for the study of neural function in animal models.

The NeuralGlider Inserter consists of a reusable Actuator that is connected to a reusable Motor. The Actuator is powered by a reusable Control Box and the Motor is powered by a reusable Motor Controller.

Refer to **Figure 1** for an illustration of the assembled device.

The NeuralGlider Inserter includes an Actuator (12) that ultrasonically vibrates a Coupler (21) that is connected to a neural implant, sold separately. This Operator's Manual depicts the Coupler used for a standard A79038-001 Omnetics connector style microwire array, however, many types of Couplers and neural implants may be used. The vibration decreases the amount of force necessary for the implant to penetrate brain tissue, thereby reducing tissue compression. This reduction in trauma can be associated with less glial scarring and increased recording yield. The Coupler is designed to connect to a neural implant during implantation and to disconnect from the neural implant after the neural implant is fixed to the skull. The Torque Screwdriver (18) allows the screws on the Coupler to be reliably tightened to a pre-set torque to ensure vibration transfer. The provided Torque Screwdriver must be used to attach the neural implant to the Coupler but other means of detachment can be used when removing the neural implant from the Coupler. The Actuator interfaces with the Coupler through a Male to Female Luer (20) that allows for 360° rotation when mated with the Luer Connector (19).

The driving electronics for the Actuator are housed in the Control Box (16). The Control Box is connected to power via the Control Box Power Cord (24) and the Jack (26). The Control Box allows for interfacing with a PC and Motor via the various USB Connections (6, 22, 23, 25). The NeuralGlider Inserter Software loaded to the PC from the USB flash drive (27) is used to control and set operating parameters. The Actuator is connected to the Control Box at the Control Box Receptacle (15) via the Actuator Cable (14).

The Actuator is connected to the Motor (4) so that the position of the neural implant can be adjusted relative to the insertion target. The Motor mounts to a standard stereotaxic frame using the Stereotactic Mounting Bar (2) and Stereotactic Mounting Bracket (1) and has a maximum linear travel distance of 10 mm. The Motor is sent commands via the Motor Controller (5), which is connected through the Motor Cable (13). The Motor Controller is powered through the Motor Control Power Supply (8), which is attached through the Motor Controller Power Cord (9) and the Motor Controller Power Supply Cord (7).

The Actuator and Motor are controlled using the NeuralGlider Inserter Software. The software allows the user to specify position, velocity, actuation on/off, and power. A USB Camera mounts next to the Actuator to view the neural implant and insertion site. The Camera Mount (11) has three axes of rotation to allow for a greater range of adjustment. There are two thumbscrews on the Camera Mount. One allows the Camera Mount to be moved about the Stereotactic Mounting Bar, while the other allows for rotation of the Camera relative to the neural implant.

FIGURE 1a: Illustration of the NeuralGlider Inserter Model 101.

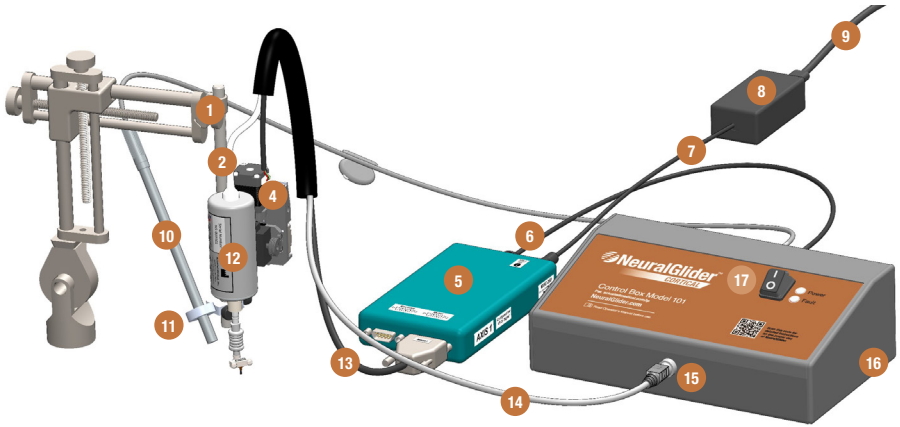


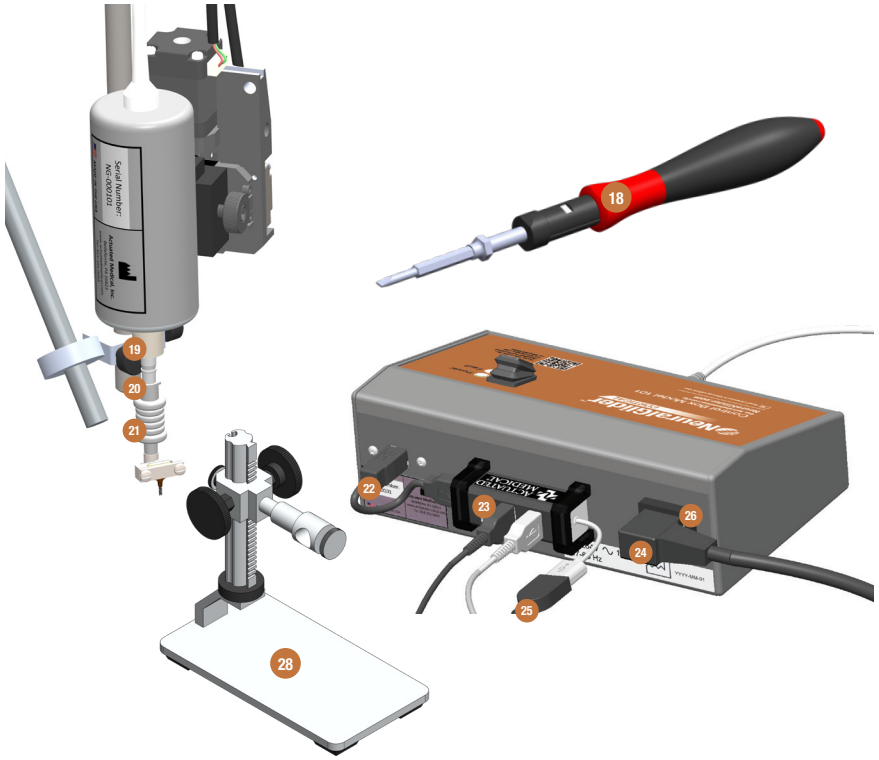
TABLE 1a: NeuralGlider Inserter Component List.

Item No.	Name	Description
1	Stereotactic Mounting Bracket	Secures the Actuator to a sterotactic frame.
2	Stereotactic Mounting Bar	Allows for the Motor and Camera to be connected to the sterotactic frame and positioned near the insertion site.
3	3/32” Hex L-Key	For adjustment of Stereotactic Mounting Bar *(Not Shown in Figure)*
4	Motor	Vertically positions the Actuator.
5	Motor Controller	Contains the driving electronics for the Motor.
6	USB Type A to Mini B Cable	Connects the Motor Controller to the USB Hub.
7	Motor Controller Power Supply Cord	Connects the Motor Controller Power Supply to the Motor Controller.
8	Motor Controller Power Supply	Reduces voltage to the Motor Controller.
9	Motor Controller Power Cord	Plugs into a standard outlet and into the Power Supply.
10	Camera	Provides visualization of the implantation site.
11	Camera Mount	Secures the Camera onto the Stereotactic Mounting Bar and allows for the adjustment of the Camera angle.
12	Actuator	Vibrates the array.
13	Motor Cable	Connects the Motor input to the Motor Controller.
14	Actuator Cable	Connects the Actuator to the Control Box.
15	Control Box Receptacle	Connector for the Actuator Cable.
16	Control Box	Contains the drive electronics for the Actuator.
17	ON/OFF Power Switch	Turns the Control Box ON/OFF.

TABLE 1b: NeuralGlider Inserter Component List.

Item No.	Name	Description
18	Torque Screwdriver	Tightens the Array Clamp screws at a torque value suitable for vibration.
19	Luer Connector	Connects the Actuater to the Male to Female Luer.
20	Male to Female Luer	Allows the Array Clamp to be connected to the Actuator with 360° of freedom.
21	Array Clamp	Connects a neural implant to the Actuater.
22	USB Jumper Cable	Connects the USB Hub to the Control Box.
23	USB Hub	Contains multiple type A USB slots to connect to both the Motor Controller and Camera System.
24	Control Box Power Cord	Connects to a standard outlet to supply power to the Control Box.
25	USB Extension Cable	Connects the USB Hub to a computer.
26	Jack	Connector for the Control Box Power Cord.
27	USB Flash Drive	Contains NeuralGlider Inserter software, drivers, and Operator's Manual. *(Not Shown in Figure)*
28	Camera Stand	A Camera Stand is included as a secondary option for mounting the Camera. This Camera Stand can be used to position the Camera at locations that are not obtainable by the Camera Mount (10).

FIGURE 1b: Illustration of NeuralGlider Inserter Model 101. (Alternate View)



5.0 Software Installation

5.1) Plug the provided USB flash drive into a USB port on the computer. See **Section 8.0** for minimum or recommended PC specifications.

5.2) Navigate to USBDIR/Installer and run the Setup Application as an administrator. If you do not have administrator privileges, contact your facility's IT department to proceed with the software installation.

5.3) If prompted that the installer may be unsafe, click the "OK" or "Yes" button to continue installation.

5.4) Follow the steps in the Installation Wizard and read any licensing agreements.

NOTE: *You may need to restart the computer after installing the .NET Framework required for the program. If this happens you must restart the installation process after restarting the computer.*

5.5) After finishing the main application installation, you will be prompted with a second Installation Wizard to install device USB drivers. Follow the steps in the Installation Wizard.

5.6) Restart the computer after the drivers are installed.

5.7) The integrated USB camera may be operated with a third-party video software. You may use a preferred video recording software that is already downloaded to your computer, or you may download a recommended software to the local drive on your computer.

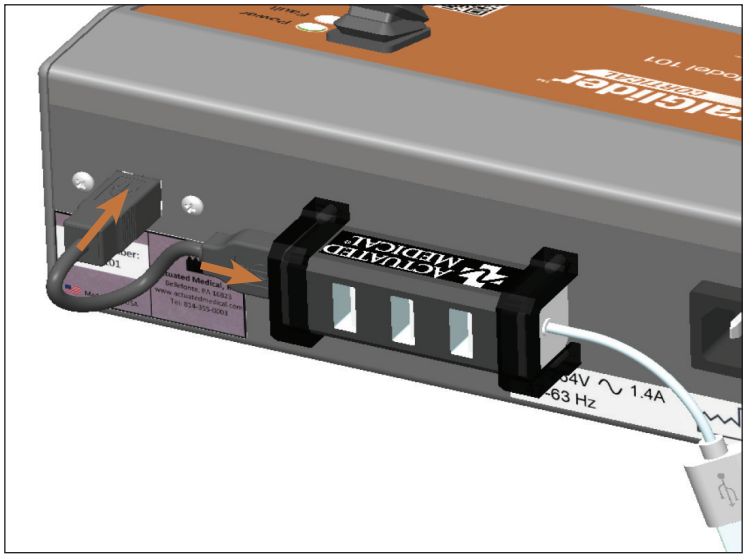
Recommended Video Recording Software:

- Plugable Digital Viewer
  http://plugable.com/pages/microscope-drivers
- Free2X Webcam Recorder
  http://www.free2x.com/webcam-recorder/
- Bandicam
  http://www.bandicam.com/downloads/

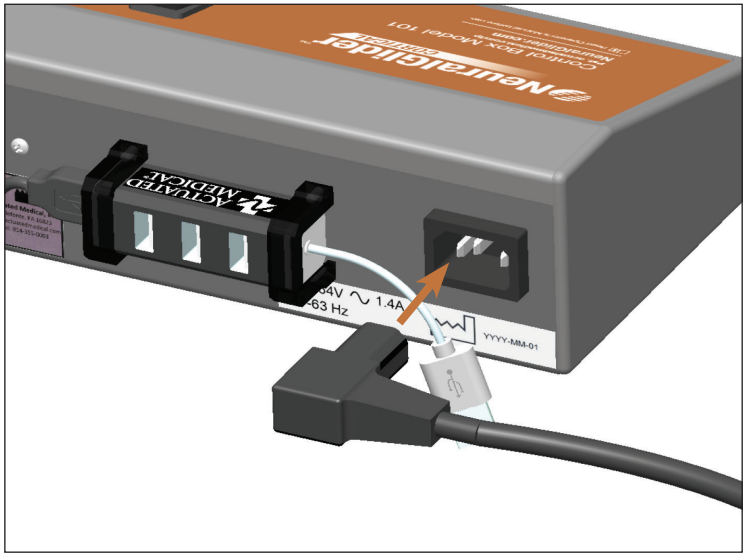
6.0 Setup Instructions

6.1) Ensure the NeuralGlider Inserter Software is installed according to **Section 5.0**.

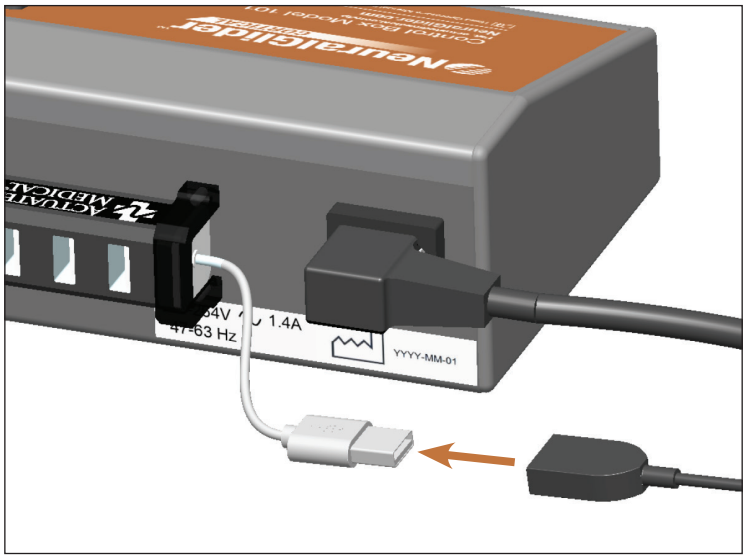
6.2) Confirm that one end of the USB Jumper Cable is plugged into the Control Box and the other end is plugged into the USB Hub.



6.3) Plug one end of the Control Box Power Cord into a standard wall outlet and the other end into the Jack on the Control Box.

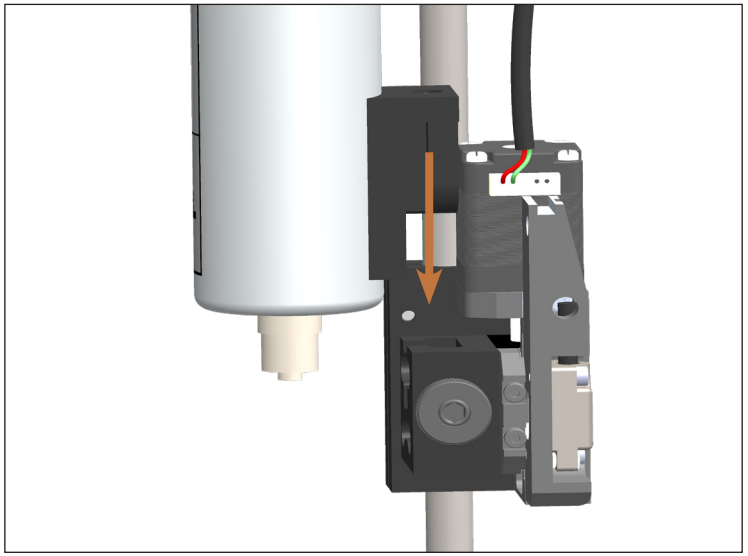


6.4) Plug one end of the USB Extension Cable into the USB Hub and the other end into a USB port on the computer that will run the NeuralGlider Inserter Software.

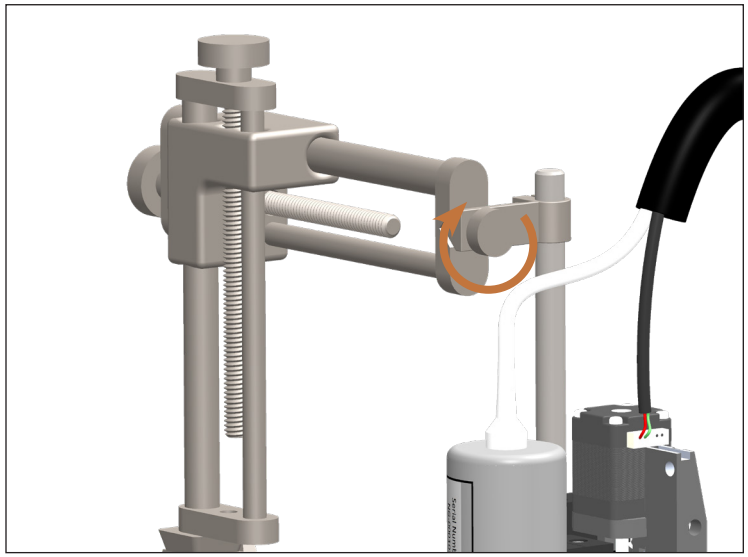


6.5) Attach the Actuator to the Motor by sliding the bracket on the Actuator into the receiver on the Motor. Then secure the Actuator in place by tightening the knob on the side of the receiver.

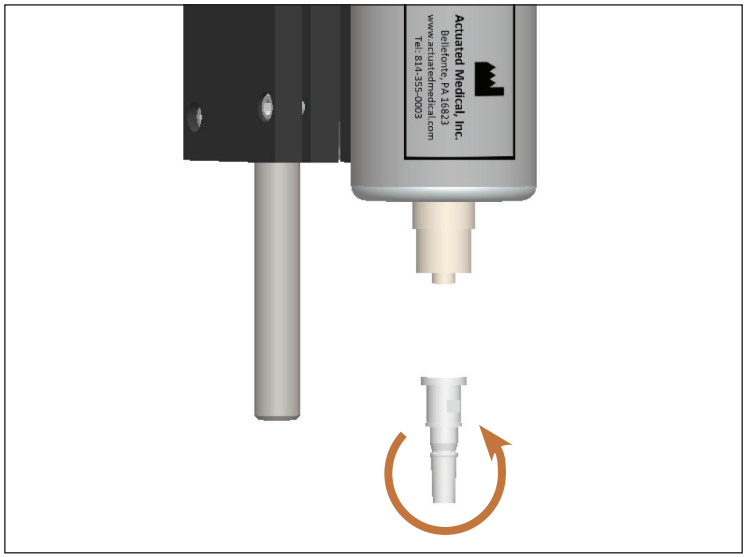
NOTE: *The Actuator must be fully inserted into the receiver before tightening the knob or the Actuator will not be held securely in place.*



6.6) Attach the Stereotactic Mounting Bracket to the stereotactic frame.

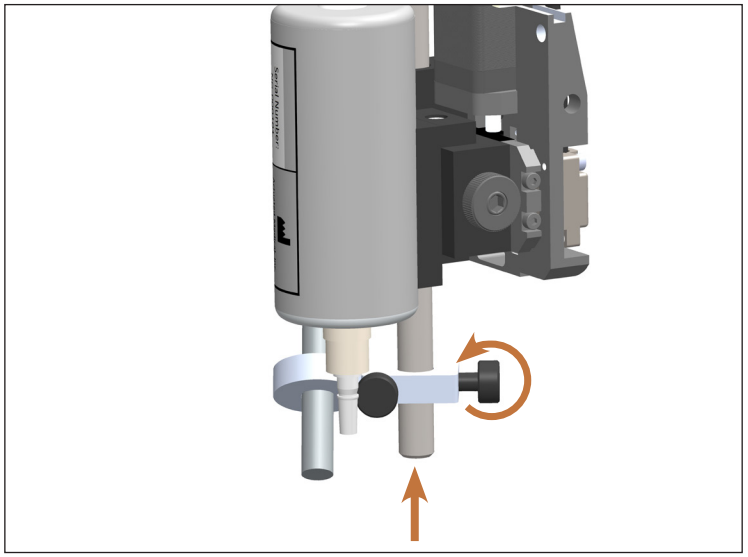


6.7) Firmly tighten the Male to Female Luer onto the Luer Connector at the end of the Actuator.

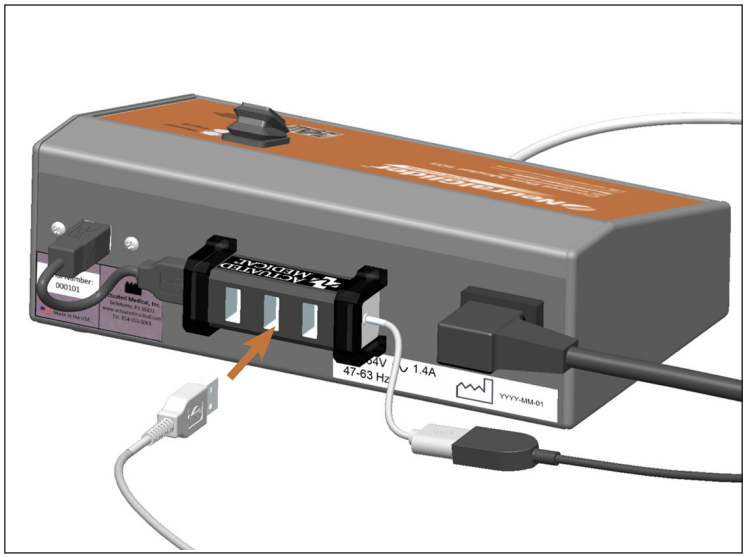


6.8) Plug the Actuator Cable into the Control Box Receptacle.

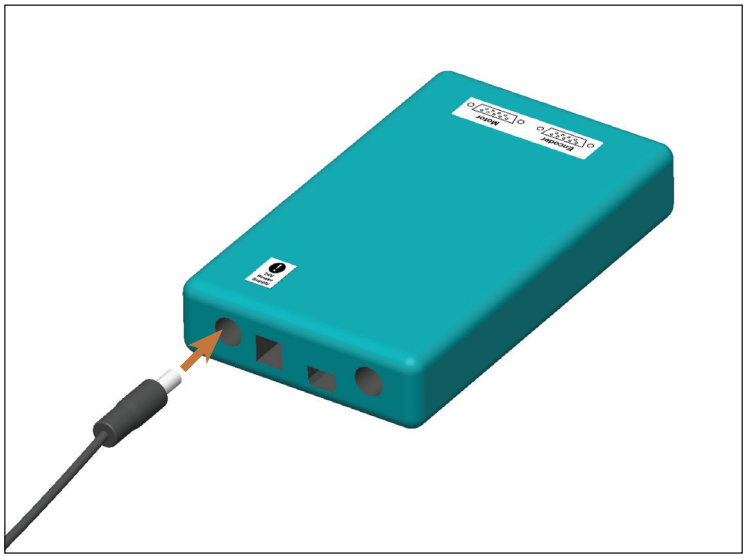
6.9) Attach the Camera by sliding the Camera Mount onto the Stereotactic Mounting Bar and tighten the knob to secure in place.



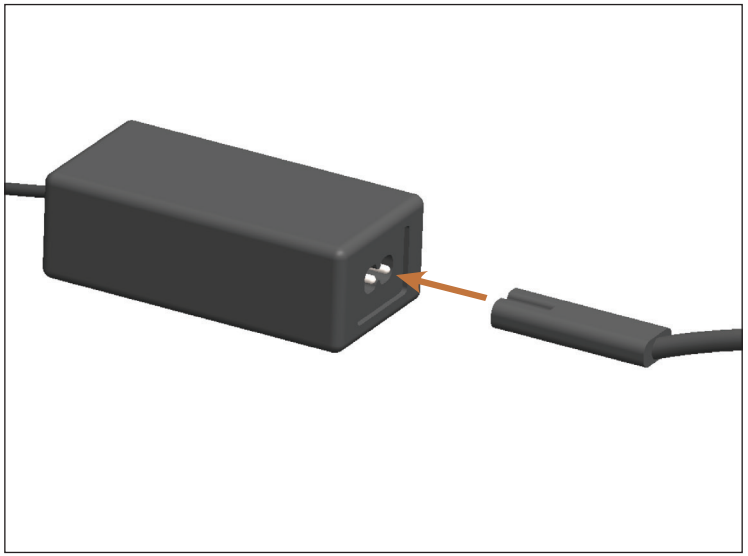
6.10) Plug the Camera into the USB Hub.



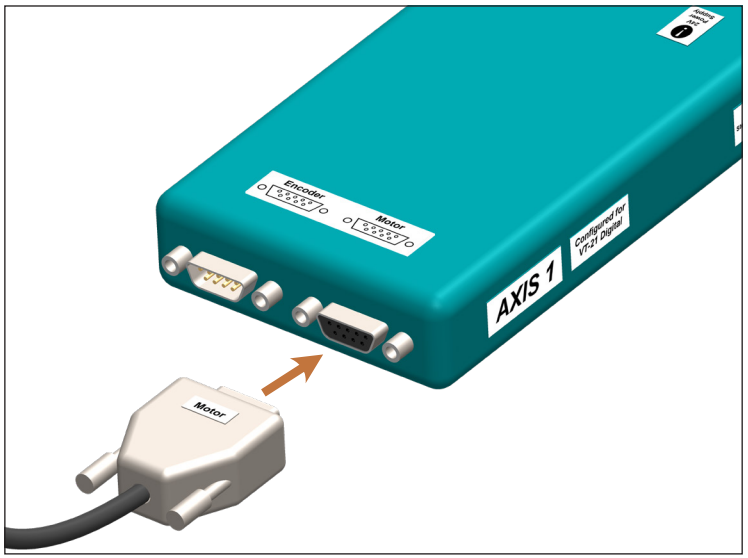
6.11) Plug one end of the Motor Controller Power Supply Cord into the Motor Controller.



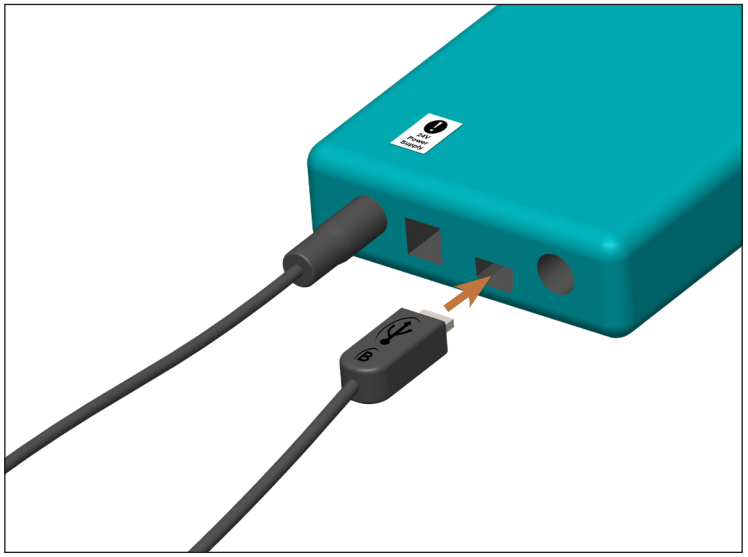
6.12) Plug one end of the Motor Controller Power Cord into the Motor Controller Power Supply if needed and the other end into a standard wall outlet (if needed).



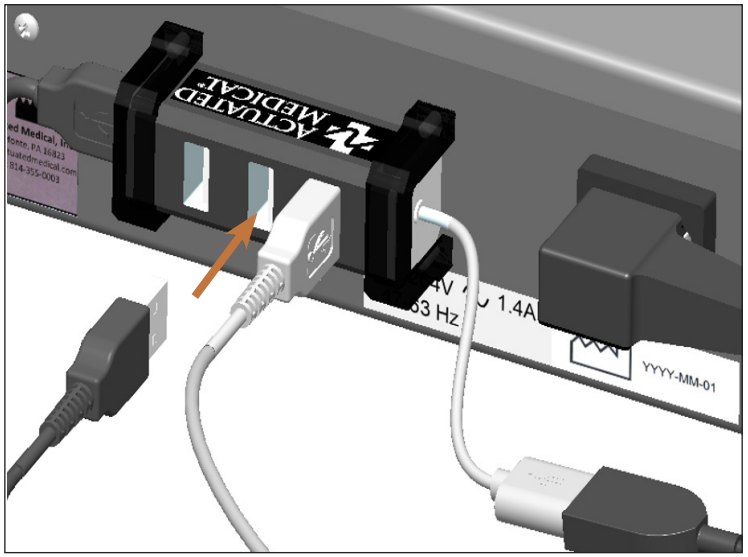
6.13) Plug the Motor Cable into the Motor Controller.



6.14) Plug the USB Type A to Mini B Cable into the Motor Controller.



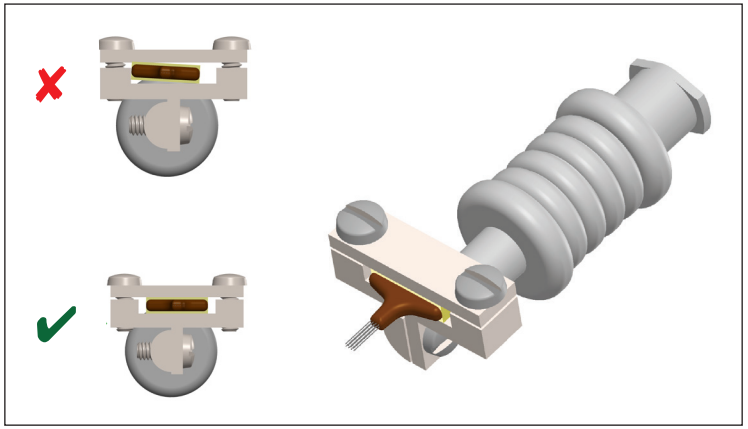
6.15) Plug the USB Type A to Mini B Cable into the USB Hub.



6.16 Turn on the Control Box by flipping the ON/OFF Power Switch to the "ON" (I) position. The power and fault lights should flash, and then the power light should remain green. Within 30 seconds, the fault light will start blinking indicating that the Control Box is not connected to software. Connection to the software is performed during operation (**Section 7.0**).

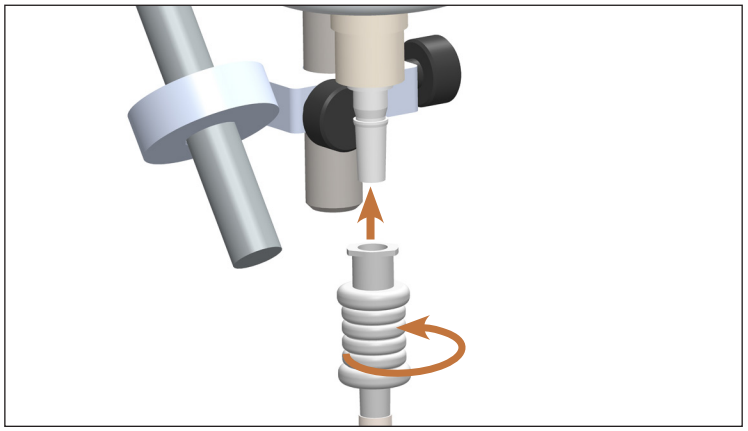
6.17) Loosen the two screws on the top of the Coupler with the Torque Screwdriver. Place an A79038-001 Omnetics connector based array in the groove. Make sure that the Omnetics connector is centered and sitting flush within the groove of the Coupler. Tighten the two screws using the Torque Screwdriver until you feel the clutch break and then the Torque Screwdriver will turn without any resistance.

__Note__: If there is excess epoxy on the Omnetics connector, make sure that the epoxy is not preventing the Coupler from coming in full contact with the faces of the Omnetics connector.



6.18) Firmly tighten the Coupler onto the Male to Female Luer located at the end of the Actuator by using a clockwise motion so that the Male to Female Luer is not loosened.

__Note__: If adjustments to the angle of the array are needed, always make adjustments by turning in a clockwise motion to assure that the Male to Female Luer and Array Clamp stay firmly tightened to the Luer Connector.



7.0 Operating Instructions

Read the Operating Instructions before operating the NeuralGlider Inserter.

7.1) Set up the NeuralGlider Inserter as directed in **Section 6.0**.

7.2) Ensure the Control Box and Motor Controller are both connected to your computer with the provided USB Extension Cable and powered ON. It is important that the Control Box is connected via USB cables before the ON/OFF Power Switch is turned to the ON (I) position.

__Note__: If not done in the proper order USB communication will be interrupted and the software will not function properly.

7.3) Run the NeuralGlider Inserter Software. The software should be located in your Start Menu after performing the software installation.

7.4) The Initialization window will open that will indicate if the communication port for the Motor was found. A pop-up will warn that the Motor may move. Press OK within the pop-up to start initialization.

7.5) The Set Home window will open to set the Motor home position. Set a desired home position by entering a numerical value from 0 to 10 and hit “Go to Home”. A home position of 5.0 mm is recommended so your ZERO position of the Motor is at the center of the range of travel.

7.6) Once the program has finished the Initialization sequence, press the “OK” button within the Initialization window, and the NeuralGlider window will be enabled.

7.7) Ensure that the indicator lights within the software next to both “Control Box” and “Motor” are bright green. If either is not, click the “Reconnect” button.

7.8) In the Save info tab at the top of the window, set the Data File Folder to a valid location and enter the File Rootname and File Suffix #.

7.11) In the Insertion Information tab, fill in the Operator ID, Test ID, and Comments text boxes if desired. This information will be saved in the data log files.

7.13) Position the stereotactic manipulator such that it is above the desired implant site. Use the dials on the stereotactic manipulator to get the array as close to the surface of the implant site as possible in Z travel.

7.14) Click the “Launch Camera” button to open the third-party video

recording software. The Camera might need to be changed to the "Supereyes" within the setting of the third-party video recording software if other integrated webcams are present.

***Note**: The first time you will provide direction to the file location of the video recording software on the local drive of your computer. The next time the "Launch Camera" button is pressed the third-party video recording software will open.*

7.15) Position and focus the Camera so that the tip of the array is in clear view. The Camera position can be adjusted in two ways. Loosening the thumbscrews allows the Camera Mount to be moved up and down on the Stereotactic Mounting Bar and the Camera angle to be rotated. Secure both knobs when finished. Pushing the Camera through the ring allows for view and focal length adjustment. To focus the Camera, turn the ribbed knob on the back of the Camera clockwise or counter-clockwise.

7.16) In the MOTOR POSITION area of the window, set the Move textbox to 0.050 mm and the Velocity textbox to 0.050 mm/s if they are not already.

NOTE: A velocity of 0.050 mm/s is recommended for all insertion procedures.

7.17) Using the "Move" arrow buttons, move the array down until it is clearly touching the insertion site.

7.18) Click the "ZERO" button. The Relative Position textbox should indicate 0.000 mm.

7.19) Move the array 0.250 mm above the site by setting the Move textbox to 0.250 mm and pressing the up arrow once. The Relative Position textbox should indicate 0.250 mm.

7.20) Click the Enable Actuation button in the INSERTION CONTROL area of the window to turn ON the Actuator.

***NOTE**: The Enable Actuation Button will indicate "OFF" before pressed, after pressed it will indicate "ON". This will enable actuation of the array.*

7.21) Using the Camera, verify that the array is visibly actuating/vibrating. If it is not, increase the Power Level by 0.10 Watt increments until visible actuation/vibration of the array electrodes is obvious and stable. Increase the Power Level by pressing the arrows next to the Power Level textbox. The range of permitted Power Levels is 0.50 - 1.50 Watts.

***Note**: When using arrays with shorter (5 mm) electrode shanks the visibility of the electrodes might be more difficult to see. In these cases, the Power Level should be set to 1.50 Watts to achieve the best performance.*

7.22) Click the Enable Actuation Button to turn OFF the Actuator.

7.23) Click the "Auto" button to go to automatic insertion mode. The indicator

light above Auto should turn bright green.

7.24) Enter the target depth of insertion in the Target Depth textbox.

***NOTE**: The depth set here is the actual depth from the surface of the insertion site, or ZERO point.*

7.25) If data logging is desired, press the Data Log button to read "ON", and select automatic or manual save mode by using the Data Log Mode checkbox.

***NOTE**: When the Data Log Mode checkbox is unchecked (Manual Mode), data will continue to log until the Log Data button is pressed again. When the Data Log Mode checkbox is checked (automatic mode), data will stop recording 15 seconds after the target depth is reached and "Save" must be pressed to save the data.*

7.26 Click the Enable Actuation button to read "ON".

***NOTE**: While in automatic mode, the Actuation indicator light will not turn ON until the auto insertion sequence is enabled after clicking "GO". Insertions can be performed using the NeuralGlider Inserter with actuation OFF if desired by leaving the Enable Actuation button "OFF".*

7.27) Set an actuation delay if desired. An actuation delay of 0 to 1 second is recommended.

7.28) Click "GO" to perform automatic insertion using the previously set parameters.

***NOTE**: If you would like to save video of the insertion, it must be done manually in the third-party software.*

7.29) Once the array has been implanted to the target depth, the Motor will stop and the Actuator will turn off.

7.30) If Data Log is "ON" and Data Log Mode is set to automatic, data recording will terminate 15 seconds after the target depth is reached. If the Data Log Mode is set to manual, then the Log Data button must be pressed to stop recording and to save data. Once data logging is complete, the Data Waiting indicator light will change to a bright green. Press "SAVE" to save the data.

7.31) Fix the array to the skull according to your institution's protocols.

7.32) After the array is securely fixed in place, use your hand to provide some support to the Coupler and loosen the two screws that are holding the neural implant in place. Make sure the neural implant is fully free from the Coupler before moving to the next step.

7.33) Switch back to Manual Mode in the INSERTION CONTROL area.

7.34) Use the "Move" arrows to retract the Array Clamp up, leaving the array in place.

TABLE 2: Recommended Software Parameter Settings for Insertions.

Recommended Software Settings			
Home Position	5.00mm	Acceleration	100.00mm/s^2
Move	0.050mm	Deceleration	100.00mm/s^2
Velocity	0.050mm/s	Actuate Delay	0.00 - 1.00 sec

8.0 Software

TABLE 3: NeuralGlider Inserter Software Requirements.

	Minimum PC Specifications	Recommended PC Specifications
Processor	Intel Pentium M	Intel Core i5
RAM	2 GB	4 GB
Disk Space	5 GB	5 GB
Operating System	Windows 7 or greater	Windows 7 or greater

Software Overview:
The software has two main modes of operation: Automated Insertion Mode and Manual Insertion Mode. The user may switch between these modes by clicking either “Auto” or “Manual”. The current active mode is indicated with an illuminated green light. The Manual Insertion Mode gives the user direct control of both the Actuator and the Motor. The Automated Insertion Mode automates control of the Actuator and the Motor based on user settings to perform controlled and consistent electrode insertions.

TABLE 4: NeuralGlider Inserter Software Description (Refer to **Figures 2a** and **2b**).

Item No.	Name	Description
1	Data File Folder	Path control where the logged data will be saved. This must be an existing folder.
2	File Rootname	The root of the name of the save file. This can be any single line string.
3	File Suffix #	The number appended to the Rootname of the save file. This must be a numeric value.
4	Auto Increment File	Checkbox that, when checked, will cause File Suffix # to increment with each successive save.
5	Position Graph	Displays the current location of the Motor relative to the full range of movement.
6	Zero location	Indicates the current zero location on the position graph.
7	Target location	Indicates the current target location on the position graph.
8	ZERO	Sets the relative zero point to the current Motor position.
9	Up arrow	Moves the Motor in the positive direction (towards the top) by the Move increment.
10	Down arrow	Moves the Motor in the negative direction (towards the bottom) by the Move increment.
11	Control Box (LED)	Indicates the Control Box status. **Green:** The Control Box is connected and in a valid state. **Red:** The Control Box is disconnected. **Yellow:** The Control Box is in a fault state.
12	Motor (LED)	Indicates the Motor status. **Green:** Motor Controller is connected and in a valid state. **Red:** Motor Controller is disconnected.
13	Actuation (LED)	Indicates the state of the Actuator. **Green:** Actuation is enabled and stable. **Yellow:** Actuation is enabled and not stable. **Dark Green:** Actuation is not enabled.
14	Writing (LED)	Indicates whether data writing is active. **Green:** Currently writing data logged file to storage. **Dark Green:** Not currently writing to storage.
15	Data Waiting (LED)	Indicates that there is data in the queue that can either be saved or discarded. **Green:** There is currently data in the queue. **Dark Green:** There is currently no data in the queue.
16	Save	Saves data to the specified file location. This control is disabled during auto insertions and when there is no data waiting.
17	Discard Data	This control is disabled during auto insertions and when there is no data waiting.
18	Manual	Control to change the insertion mode to Manual.
19	Log Data	Controls data logging. Can display ‘ON’ or ‘OFF’. **In Manual Mode, ‘ON’** immediately begins data logging, given the Data File Folder is valid. **In Auto Mode, ‘ON’** will start data logging when the automated insertion begins. **‘OFF’** indicates there is no data logging.

Software Description continued on next page

20	Power Level	Sets the power level of the Actuator. The minimum value is 0.5 Watts and the maximum value is 1.5 Watts.
21	Enable Actuation	Controls the Actuator. Can display 'ON' or 'OFF'. **In Manual Mode, 'ON'** immediately turns the Actuator on. **In Auto Mode, 'ON'** will turn the Actuator on when the automated insertion begins, after the specified Actuation Delay.
22	Operator ID	A metadata field that will be put into the data log files. This string is intended to identify the insertion operator.
23	Test ID	A metadata field that will be put into the data log files. This string is intended to identify the insertion test/experiment name.
24	Comments	A metadata field that will be put into the data log files. This string can be used to save additional comments about the insertion.
25	Relative Position	Indicates the current position of the Motor relative to the zero point.
26	Move (Increment)	Sets the distance moved when the Motor is positioned in Manual Mode. The minimum value is 0.001 mm and the maximum value is 10 mm.
27	Velocity	Sets the velocity at which the Motor moves. The minimum value is 0.001 mm/s and the maximum value is 5 mm/s.
28	Edit Acceleration	Checkbox to allow editing of the Acceleration and Deceleration controls.
29	Acceleration	A control to set the acceleration at which the Motor moves. The minimum value is 1 mm/s^2 and the maximum value is 500 mm/s^2.
30	Deceleration	A control to set the deceleration at which the Motor moves. The minimum value is 1 mm/s^2 and the maximum value is 500 mm/s^2.
31	STOP	Emergency stop button. It will stop both the Motor and Actuator.
32	Launch Camera	Launches a third-party camera software.
33	Reconnect	Reconnects both the Control Box and Motor USB communication data streams.
34	Exit	Closes out of the application. It is preferable to close out of the application using this button over the Close button in the window pane, as this puts all of the external devices to a known state.
35	Auto	Sets the insertion mode to Automatic.
36	Data Log Mode	Only visible in Auto Mode. Sets the data log mode to either automatic or manual logging termination. **Automatic Data Log Mode:** Data logging automatically saves 15 seconds after an insertion is finished. **Manual Data Log Mode:** Data logging is manually terminated by the user by clicking the Log Data button (will display 'OFF' when data logging is terminated), then the data will be saved.
37	Actuation Delay	Only visible in Auto Mode. Sets a delay time for actuation to begin following the start of an automatic insertion. NOTE: To delay actuation to a targeted Motor position, the Actuation Delay time can be calculated from the Motor velocity.
38	Target Depth	Only visible in Auto Mode. Sets the insertion target depth.
39	GO	Only visible in Auto Mode. Initiates an automated insertion.
40	Progress to Target	Only visible in Auto Mode. Displays the percent of insertion completion during an automated insertion.

FIGURE 2a: Illustration of NeuralGlider Inserter Software.

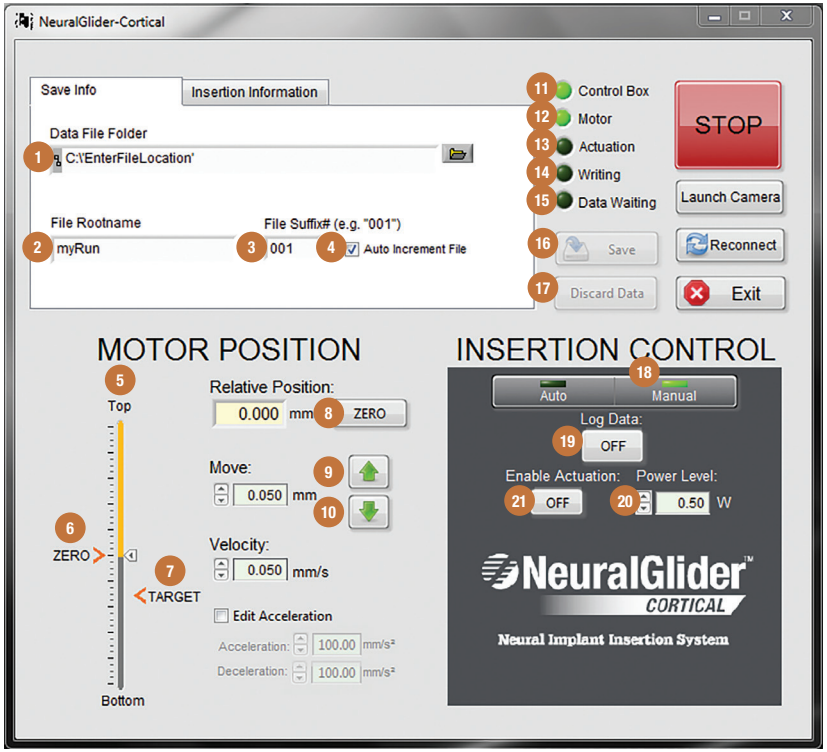
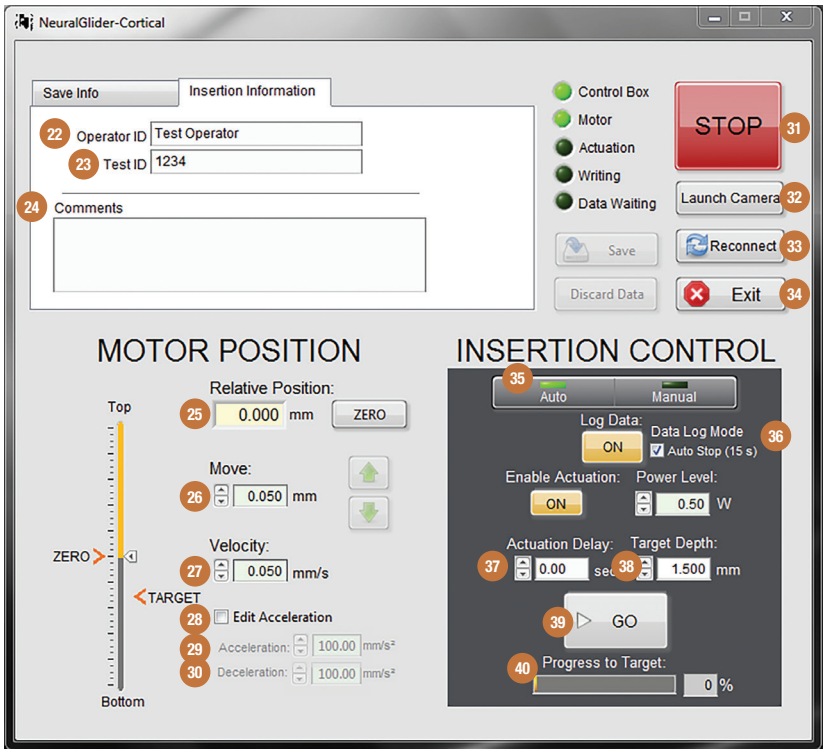


FIGURE 2b: Illustration of NeuralGlider Inserter Software.



9.0 Cleaning Instructions

Turn ‘OFF’ and unplug the NeuralGlider Inserter prior to cleaning.

Thoroughly clean the NeuralGlider Inserter after each use.

Clean the Control Box, Actuator, Motor, Motor Controller, and Camera by wiping all exterior surfaces with (1) a cloth dampened with isopropyl alcohol or with (2) disinfectant wipes. Clean the Coupler by immersing in 70% isopropyl alcohol for two minutes. DO NOT submerge the Control Box, Actuator, Motor, Motor Controller, or Camera in liquid. DO NOT subject to autoclave sterilization.

10.0 Maintenance

Other than careful cleaning of the NeuralGlider Inserter after each use, the NeuralGlider Inserter does not require maintenance.

11.0 Storage

Store the NeuralGlider Inserter in a clean, dry area. It is recommended that the NeuralGlider Inserter be stored at temperatures between -20°C (-4°F) and 60°C (140°F) and relative humidity between 25% and 80%. Do NOT exceed temperatures below -20°C (-4°F) or above 60°C (140°F) or relative humidity of 25% and 80%.

12.0 Return Policy

Actuated Medical takes pride in the quality of our products. If the device is found to be defective, contact our Customer Service Department at +1 (814) 355-0003 ext. 117 for prompt replacement. You will be provided with a Return Authorization (RA) number and return shipping information. All returns must be accompanied by an RA number and reason(s) for return.

13.0 Disposal

The NeuralGlider Inserter is classified as Waste Electrical and Electronic Equipment (WEEE). Do not dispose of the device with normal domestic waste at the end of its life. Please take it to an official recycling point to be properly disposed.

14.0 Troubleshooting Guide

Issue	Solution Options
The array is not moving/vibrating after the Enable Actuation ‘ON’ button is pressed.	The power level might not be set to the required wattage to initiate vibration. The power level can be adjusted between 0.5 W and 1.5 W. The Coupler might not be attached correctly to the Luer. Remove the Coupler and firmly place the Coupler on the Male to Female Luer. The array might not be clamped correctly in the Coupler. Using the provided Torque Screwdriver, tighten the screws on the Coupler. The Power Cord may not be securely plugged in to the Control Box. Turn the ON/OFF Power Switch ‘ON’ then ‘OFF’ (i.e., cycle the power). If the array still does not move/vibrate, then contact Actuated Medical’s Customer Service Department for instructions.

Troubleshooting Guide continued on next page

The Control Box Fault light is flashing.	The Control Box yellow fault light will flash until communication between the Control Box and the software is established. Establish connection by pressing the Retry All within the Initialization window or Reconnect within the NeuralGlider window.
The Control Box makes a series of beeping sounds.	The Control Box is overheating. The Actuator can be vibrated at 1.5 W for 15 minutes. Then it must be cooled for 20 minutes before additional usage. Power Switch to the ON (I) position. The USB cable from the Control Box must be connected before the Control Box can be powered ON. If the problem continues contact Actuated Medical's Customer Service Department for instructions.
No COM ports were found during initialization.	The USB ports may not be firmly in place. Reconnect the USB. Windows may not recognize the COM ports as known devices. Uninstall the drivers for the Unknown Devices in the Device Manager and reconnect the USB. The USB FTDI drivers may be corrupted or missing. Reinstall the FTDI device drivers using the executable located in the NeuralGlider Cortical install directory ([Install Directory]/ NeuralGlider Cortical/CDM21228_Setup.exe).
The Motor was not found during initialization.	The USB port may not be firmly in place. Reconnect the USB. Either select the Motor Controller COM port from the drop-down list and click the "Retry Motor Controller COM" button, or press the "Retry All" button in the Initialization window. The Motor Controller may be in a faulty condition. Restart the Motor Controller (power cycle by unplugging it and replugging it in) and reconnect the USB. Either select the Motor Controller COM port from the drop-down list and click the "Retry Motor Controller COM" button, or press the "Retry All" button in the Initialization window.
The Control Box was not found during initialization.	The USB port may not be firmly in place. Reconnect the USB. Either select the Control Box COM port from the drop-down list and click the "Retry Control Box COM" button, or press the "Retry All" button in the Initialization window. The Control Box may be in a faulty condition. Restart the Control Box and reconnect the USB. Either select the Control Box COM port from the drop-down list and click the "Retry Control Box COM" button, or press the "Retry All" button in the Initialization window.
The Motor was found, but the Motor is not moving.	The top or bottom limit of the Motor may be reached. Click the Stop button and move the Actuator up or down. The Motor Controller may be in a faulty condition. Restart the Motor Controller and reconnect the USB. Either select the Motor Controller COM port from the drop-down list and click the "Retry Motor Controller COM" button, or press the "Retry All" button in the Initialization window. Resart the software.
The light on the Control Box is yellow.	The Control Box is in a fault condition. Restart the Control Box and ensure the Actuator is attached to the receptacle on the front of the Control Box. If the problem persists and everything is connected, contact Actuated Medical's Customer Service Department for further instructions.
The Control Box is connected, but actuation is not enabled.	The Control Box may be in a faulty condition. Restart the Control Box and reconnect the USB connection by pressing the Reconnect button on the NeuralGlider window to reestablish communication. If the problem persists, restart the software.
The wrong software was selected for the Camera.	Once the camera software has been chosen on a particular user account it will be remembered. To force the program to "forget" the camera software, stop the NeuralGlider Inserter Software if it is running and press the "Windows Key" plus "R" to open a run prompt in Windows. In the "Open" field, type "%appdata%" and press enter. Navigate to the NeuralGlider folder in AppData/ Roaming. Delete the file either named "camera" or "camera. path". The next time you run the NeuralGlider Inserter Software and press the "Launch Camera" button, the program will allow you to select a new third-party camera software.
The Camera is not detected in the video software.	The Camera may be in a fault condition. Reconnect the USB connections and try to run the camera software again. If it persists, try using another camera application to view the video feed. If it still persists, contact Actuated Medical's Customer Service Department for further instructions.

15.0 Technical Data

15.1) **Environmental Conditions that Affect Use**

- **Operating Conditions:** From 0°C (32°F) to 35°C (95°F) Relative Humidity from 30% to 75%
- **Transportation and Storage Conditions:** From -20°C(-4°F) to 60°C (140°F). Relative humidity from 25% to 80%.

15.2) **Device and/or Packaging Symbols**

Symbol	Meaning	Symbol	Meaning
	Temperature Limitations		Read the documentation
NON-STERILE	Non-sterile		Alternating Current
LOT	Batch		Manufactured Date
	Caution		Manufacturer

15.3) **Accessories**

- **Control Box Power Cord**
  Shielded, IEC320 Connector, RoHS Compliant.
- **USB Extension Cable**
  Shielded, USB 2.0 Cable A Female to A Male 6.00’ (1.83m), RoHS Compliant.
- **Motor Controller Power Cord**
  Unshielded, 10A 125V MAX, CEE 7/16 To IEC320-C8 6.00’ (1.83m), RoHS Compliant.
- **Motor Controller Power Supply**
  100-240 Volts DC 50-60Hz 1.2A MAX, IEC320-C8 Connector, RoHS Compliant.
- **USB Type A to Mini B Cable**
  USB Cables / IEEE 1394 Cables USB A-B 28/28 BLACK .16 M, RoHS Compliant.

⚠ Use of Power Supplies and Power Cords other than those specified in **Section 15.3** may result in improper functioning of the NeuralGlider Inserter.

16.0 Limited Warranty

Actuated Medical, Inc. (“Manufacturer”) makes certain limited warranties set forth in this Limited Warranty regarding the following products (the “Products” and each a “Product”): NeuralGlider Inserter Model 101.

Manufacturer warrants to the purchaser of the Products (“Customer”) that the Products will be free from defects in material and workmanship per AMI Product specifications for a period of 13 months from the date of purchase (the “Warranty Period”). The foregoing limited warranties are solely to and for the Customer’s benefit.

Limited Warranties do not apply where any Product (a) has been subjected to abuse, misuse, neglect, negligence, accident, improper testing, improper installation, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions or use contrary to any instructions issued by Manufacturer; or (b) has been reconstructed, repaired or altered by persons other than Manufacturer or its authorized representative.

During the Warranty Period, regarding any defective Product deemed defective by the Manufacturer, Manufacturer’s liability under any Limited Warranty is discharged, in Manufacturer’s sole discretion and at its expense, by (i) repairing or replacing the defective Product; or (ii) crediting or refunding the price of the defective Product, less any applicable discounts, rebates or credits.

All claims for breach of a Limited Warranty must be received by Manufacturer no later than fifteen (15) calendar days after the expiration of the Warranty Period.

THIS LIMITED WARRANTY SETS FORTH CUSTOMER’S SOLE REMEDY AND MANUFACTURER’S ENTIRE LIABILITY FOR ANY BREACH OF ANY WARRANTY RELATING TO THE PRODUCTS. EXCEPT FOR THE EXPRESS LIMITED WARRANTIES DESCRIBED IN THIS LIMITED WARRANTY, NEITHER MANUFACTURER NOR ANY PERSON ON MANUFACTURER’S BEHALF HAS MADE OR MAKES ANY EXPRESS OR IMPLIED REPRESENTATION OR WARRANTY WHATSOEVER, INCLUDING ANY WARRANTIES OF: (i) MERCHANTABILITY; (ii) FITNESS FOR A PARTICULAR PURPOSE; (iii) TITLE; (iv) NON-INFRINGEMENT; OR (v) PERFORMANCE OF PRODUCTS TO STANDARDS SPECIFIC TO THE COUNTRY OF IMPORT, WHETHER ARISING BY LAW, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE OR OTHERWISE, ALL OF WHICH ARE EXPRESSLY DISCLAIMED.